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PCT

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(54) Title: TELEMEDICINE			
(57) Abstract			
<p>Automatic test tracking analysis and reporting are provided by an automated process and computer system, which can provide a global communications network, for the convenience of patients, health care providers and public health agencies to lower health care costs. Advantageously, the speedy accurate process and system can be used to detect many types of infectious diseases, chronic diseases, genetic diseases, nutritional deficiency, environmental and general health problems, fertility, mental disorders, drug abuse, allergies, etc., as well as to automatically administer non-invasive tests, such as vision tests, hearing tests, and cognitive function tests to monitor the progress of Alzheimer's disease. Samples to be tested can be conveniently collected by the patient or by others and placed in a test kit at the patient's home or other location remote from a medical facility. The sample can be tested in a laboratory or at the patient home or other remote site. The test results and patient profile medical history can be inputted into the system or network and compared with data bases of diseases, disorders, treatments, care plans, nutritional supplements, and medicine. The process and system can transmit an analysis and proposed treatment to the patient's physician or health care provider for approval or change before the test report and recommended medicine and treatment are sent to the patient. The process and system are also useful for automatic test tracking and reporting to public health organizations.</p>			

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TELEMEDICINE

BACKGROUND OF THE INVENTION

This invention pertains to test reporting and, more particularly, to an automatic test reporting process and system.

Medical tests and other types of tests traditionally require the patient or other person being tested to travel to a medical facility or other test site. This is inconvenient and cumbersome for many patients and test subjects, especially when they are elderly, very young, infirm, have difficulty in walking or traveling, live far away from the medical facility or test site, or when transportation is not readily available. Furthermore, patients or test subjects often have to wait at their doctor's office or other test site, which is inconvenient, time consuming and frustrating.

From a viewpoint of the medical facility or other testing facility, tests are generally administered by one or more persons with the assistance of facilitators and others. The use of many employees in the test process greatly increases the costs of tests, because of salaries, benefits, insurance, workmen's compensation, etc. Current test procedures can be costly and burdensome to test subjects, as well as the testing facility.

For many types of medical tests, such as tests for human immunodeficiency virus (HIV) and genetic disease predispositions, patients usually prefer that their identity be kept secret or confidential, because of actual or perceived repercussions from their families, relatives, friends, neighbors, classmates, employer, fellow workers, associates, government officials, insurers, health care officials and the press. A call routing and handling system for conveying confidential medical test results information to anonymous callers has also been developed in which the caller can telephone the system and receive HIV test result information or status information from an automated system after providing their personal identification number (PIN).

Patients with chronic diseases, i.e., diabetes, asthma, heart disease, etc., find it difficult to comply with treatment regimens, such as diet, testing and medication schedules. Lack of compliance leads to costly, preventable hospitalizations and complications. Effective methods to assist these patients in compliance are not generally available. Presently, patients have to regularly schedule appointments and periodically visit clinics dedicated to specific chronic disease states such as diabetes and coumadin clinics. These clinics provide patient education sessions with nurse educators, testing capability, and general advice on disease management. At a clinic, the patient will see a physician and/or a nurse and undergo an examination. Blood is drawn from the patient and tested in a laboratory which, often times, is at a site remote from where the blood was drawn. The laboratory results are reported to the physician who later telephones or meets with the patient to discuss the test

results and adjust the patient's medication, as necessary. The disadvantages of this system include: (1) inconvenience, time and cost for the patient and provider; (2) patients find these visits depressing and cumbersome, especially in cases where test results are normal and no change in regimen is therefore required; (3) patients often miss scheduled appointments, thereby losing any potential compliance assistance from the system; (4) there is usually no feedback and follow-up other than the clinic visits; (5) patients rarely receive help meeting regimen requirements on a day-to-day basis; (6) tests performed in clinics are not generally available on a home-use basis since many of these tests require some level of professional interpretation to adjust patient medication or treatment regimens; and (8) physicians and nurses often spend time with patients who are in good health and/or comply with their treatment regimens, and therefore do not need direct professional attention.

Physicians sometimes do not comply with patient "treatment guidelines" or "care maps", which describe detailed treatment regimens for a particular ailment, because of, for example, their busy schedules. Additionally, care maps simply may not exist for a given ailment. Lack of adherence to care maps or lack of care maps reduces the effectiveness of treatment and can cause costly preventable hospitalizations and complications. Presently, there is a lack of an effective method for helping physicians follow treatment guidelines and a lack of an effective method for generating care maps in cases where none exist. The disadvantages of current procedures include: (a) miscommunication or lack of communication among physicians regarding care maps or treatment guidelines; (b) inadvertent failure to comply with care map pathway or treatment guidelines; (c) lack of time and misunderstanding of care maps and treatment guidelines; (d) development of care maps or treatment guidelines is expensive for integrated health systems and manage care organizations; and (e) lack of compliance with guidelines leading to reduced health care quality, increased patient costs, and adverse patient outcomes.

Many consumers employ the services of a health care provider for professional diagnosis and treatment in an appropriate manner. On the other hand, some consumers ignore personal health issues to their detriment, or at the other end of the spectrum, some consumers seek the assistance of a health care professional too often. These latter cases have many disadvantages. For example, consumers may needlessly spend money on an unnecessary trip to see a health care provider; health care providers' time is wasted seeing patients who do not need to be treated; consumers are angered after seeing a health care professional who tells the consumer "nothing is wrong"; and consumers may aggravate a disease state by failing to appropriately visit a health care provider which may result in costly treatments and hospitalizations which could have been avoided.

Outside the United States, health care is largely government financed. As health care costs are rising, governments are reducing and limiting levels of health care. Many governments are seeking ways to decrease the frequency of patient visits to physicians and hospitalizations. Governments are sending patients for regular visits to health care providers, but reduce allowable or reimbursed patient testing and other diagnostic services.

To further reduce expenses, governments have undertaken the development of care maps and disease treatment guidelines to which health care providers must adhere. Unfortunately, patients are not always cognizant of the care maps to which health care providers must adhere. As a result, patients are unaware of changes in service and/or reimbursement allowances for those services which may lead to an increase costs to the patient.

As the population is aging, the risk of developing age related problems, such as osteoporosis increases. Today, consumers have no effective way to judge their level of development of these problems and have little assistance in knowing appropriate action to be taken. The situation is currently handled in one of many ways: (1) consumers visit a health care provider for professional diagnosis and treatment; (2) consumers attend community health fairs or events where screening for conditions associated with aging occur; or (3) consumers visit pharmacies where screening for conditions associated with aging occur. The health care provider often conducts non-invasive tests, such as vision tests and hearing tests, as well as drawing blood to screen for conditions associated with aging such as, for example, diabetes, prostate cancer, and osteoporosis. The patient is given the test results directly or, more often, is sent home to await results. Once the test results are compiled, the provider recommends appropriate action. The disadvantages of the current procedure include: (a) cost and inconvenience for the patient;

(b) lack of good patient history and medical record keeping at health fairs and pharmacies to indicate the patient's baseline or normal conditions; (c) lack of confidentiality for patients; and (d) excessive cost to the health care provider to see healthy patients or conduct health screening on a mass market basis.

In the United States, managed care enrollment is increasing but consumers have less control over their health care decisions and are seeking to regain control. Consumers desire information about their health status and education about various maladies to make informed health care decisions. Many employers in the United States offer employees a variety of managed care and indemnity plans to cover employees' health care needs, but plans differ in coverage and costs to the employee. Employees must decide which programs are appropriate for themselves and their families based upon program cost and employee and family health status. Today employees often make decisions empirically based upon the plan availability, enrollment and participation costs, and expected medical expenses. The disadvantages of current methods include: (a) employees may be "over

covered" or "under covered" for their health care; (b) employers may spend money offering plans of little value to the majority of employees; (c) employees do not have a convenient, cost effective mechanism for verifying the health status of their families; (d) employees experience anxiety in the uncertainty of health care plan decisions; and (e) because many employees and physicians switch programs on an annual basis, there is no central depository for an employee's health care records, and employees must pick-up records from one physician and transfer the records to another physician, which is inconvenient and can cause loss of information.

Managed care organizations are trying to reduce overall costs per enrolled head count. This can be accomplished by better information management, decreasing use of specialists, minimizing visits to primary care providers and reducing unnecessary hospitalizations. Preferably, cost reductions are achieved without reducing the quality of health care.

To reduce costs, health care organizations often place caps and/or controls on fees for health care services. Judgment on a patient's need for services is usually made by an administrative gatekeeper. The "gatekeeper" is typically a physician known as a "primary care physician". Procedurally, the physician sees the patient for laboratory testing and other diagnostic services to assess treatment needs, then submits paperwork to an administrator for approval to provide specific services. These procedures can cause problems including: (a) miscommunications or lack of communications regarding this gatekeeper function and requirements; (b) labor intensive and time consuming administrative paperwork; and (c) expensive and time-consuming visits to the gatekeeper.

Domestically, the budgets of U.S. Government Public Health organizations are being reduced. Public health organizations need to meet budgetary limitations, while addressing health concerns like HIV, sexually transmitted diseases (STD) and drug abuse. The Center for Disease Control (CDC) determines the charter of US Public Health. This charter is large and comprehensive, addressing a plethora of public health issues. The charter includes, but is not limited to: diagnosis, treatment, counseling, tracking and reporting for infectious diseases, sexually transmitted diseases, substance abuse; as well as investigation, tracking, and community notification of outbreaks of environmentally borne diseases, such as E. coli, hepatitis A, encephalitis; and detecting the presence of and overseeing abatement of environmental hazards, such as pollution, lead and asbestos.

Much of the data used by the CDC to track and investigate diseases and the like comes from public health agencies. Unfortunately, due to budgeting and priority conflicts, data gathering and management are handled manually in many public health facilities. This is inefficient, inadequate, time and labor intensive, and fraught with error and data loss. Inefficient data management often forces public health facilities and the CDC to take a blanket approach rather than a focused targeted approach to health screening, environmental

abatement and treatment. As a result, money is lost in broadly curing a problem when a more focused cure would suffice.

Some consumers with chronic diseases want a "mother hen" to help them comply with treatment regimens, such as diet, testing and medication schedules. These consumers regularly schedule and visit clinics where samples are taken and sent to a medical laboratory for testing. Results from these tests are then reported back to the clinic. Given the number of trips the patient takes to the clinic as well as the system for obtaining and reporting test results, the present procedures at specialty clinics are inconvenient, time-consuming and expensive. In addition, patients often miss scheduled appointments and, often times, clinics do not remind patients of there appointments thereby losing any potential compliance assistance from the system. Moreover, patients receive little assistance from the clinic in meeting regimen requirements on a day-to-day basis.

Consumer diagnostics are not widely accepted because consumers have little or no knowledge about the meaning or consequences of a test result without input from a health care professional. Accordingly, even though a sample can be tested in the privacy of ones home, a trip to a health care provider is nevertheless necessary to interpret or give meaning to the result in spite of the fact that the test result may in fact be normal.

Hence, there is a need for a process and system for storing and dispensing medical information in a manner that saves consumers and health professionals time and money by dispensing with unnecessary meetings between these parties.

SUMMARY OF THE INVENTION

The present invention provides an automated test reporting system that eliminates unnecessary meetings between consumers and health professionals in an economical and convenient manner. In the novel process and system, the results from at least one test or testing kit, such as from a remote sample collection and/or testing kit, are inputted into a central processing unit (CPU), which can track, analyze, compare, or otherwise manipulate the results. The results or information derived from, related to, or based on the test results are reported to a designated person or agency such as a patient, public health official, health department employee, official of the Center for Disease Control, physician (medical doctor), staff member of a hospital, trauma center personnel, health care provider, a managed care provider, nurse, dentist, insurance representative, environmentalist, customer, student, pharmacist, medical supply house, nutritionist, hygienist, psychiatrist, psychologist, optometrist, or audiologist. Hence, the CPU can select a person or agency based upon inputted test result information. Desirably, the identification of the person is verified by the system (CPU) before the person is provided with the test results, or information related to the results.

The CPU can be a: microprocessor, computer, computer system, computer network, a semiconductor chip (computer chip), circuit board, control board, programmable controller, logic controller, mainframe, or data processing center. The test results can be inputted into the CPU by a: keyboard, telephone, modem, cellular phone, an internet connection, world wide web link, computer, touch screen display, analyzer, or data processing center.

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Based upon manipulations performed by the CPU, the CPU selects and contacts an appropriate person or agency through the use of, for example, transmitters, receivers, telephones, cellular phones, internet sites, televisions, beepers, closed circuit monitors, computers, display screens, telephone answering machines, facsimile machines, or printers. Connections between the CPU and appropriate body or bodies can be facilitated with, for example, telephone lines, computer networks, internet connections, satellite communication systems, and global communications networks.

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In the inventive process and system, a sample can be collected by a patient, customer, public health official, assistant or other collector. The sample can be: urine, saliva, breath, hair, fingernails, buccal cells, oral fluids, stool, skin, sweat, nasal fluids, mucous, semen, vaginal secretions, blood, ocular fluids, eye swabs, or ear wax. In one embodiment, the sample is tested by a laboratory which may be remote from the sampling site. In another embodiment, the sample is tested by the patient, customer, nurse, public health official, which may be at the sampling site.

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Non-invasive tests, such as a hearing test, a vision test, a reading test, or a cognitive function test to monitor progression of Alzheimer's disease, can be administered by the system (CPU). This can be accomplished by electronically transmitting the test to a receiver in proximity to the person being tested, such as a: television, monitor, computer screen, internet address, telephone, cellular phone, beeper, flat panel display, light emitting diode (LED) screen, active matrix display screen, passive matrix display screen, or liquid crystal display.

The process and system can be used to detect, monitor and screen many types of infectious diseases, chronic diseases, genetic diseases, nutritional deficiencies, environmental and general health problems, fertility, mental disorders, drug abuse, allergies. The process and system provides for better monitoring of a chronic disease patient's status, allowing early intervention to avoid future complications. Furthermore, the novel process and system can lead to better patient compliance for chronic disease treatment regimens by regularly contacting persons to remind them to follow a particular treatment or sampling regimen. Better patient compliance can reduce aggravation of the disease, complications and hospitalizations.

The inventive process and system can also save physicians time by sending physicians recommended care plans thereby automating portions of the care map, reducing the

physicians' need to remember details of the care map and helping the physicians better comply with care maps and treatment guidelines resulting in improved patient outcomes. Additionally, the system can be employed to update and modify or create care maps. The process and system can also analyze medical and demographic information on the patient vis a vis statistically significant outcome information on other patients of similar demographic and disease backgrounds to assist health care providers and public health services diagnose or treat diseases. This allows the physician to make better decisions on patient management, ultimately improving quality of care and reducing treatment costs. Desirably, the novel process and system enable patients to manage their disease or take tests at home. The improved process and system are also helpful to individuals in selecting a health care provider.

A more detailed explanation of the invention is provided in the following detailed description and appended claims taken in conjunction with the accompanying drawings.

15 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a process flow diagram of an automatic test reporting process in accordance with principles of the present invention; and

Figure 2 is a block flow diagram of an automated test reporting process and system for non-invasive tests in accordance with principles of the present invention.

20 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An automatic test reporting process and system for telemedicine provides rapid accurate automatic, comprehensive test tracking, analysis and reporting for the convenience of the consumer and health care organizations. Desirably, the economical process and system lowers health care costs and are automated, safe and reliable.

In the process and system, a test kit 10 (Figure 1) can be obtained by or for a patient or customer and brought to a site such as the patient's home, place of business, store, or other location remote from a site that performs tests or interprets test results such as a medical facility, hospital, trauma center, or doctor's office.

The term "test kit" is intended to encompass means for remote sampling as well as means for remote testing. Means for remote sampling are well known in the art and may include, for example, piercing instruments (such as lancets); and/or collection receptacles (such as cups, pouches, bags, bibulous or absorbent materials and the like). Further examples of sample collection instruments or collection receptacles include, for example, swabs, cotton gauze, nail clippers, scissors, cups, bottles, test tubes, capillary tubes, petri dishes, condoms, bags, gloves, tape, paperboard, cardboard, dermatological patches, eye droppers, pipettes, and the like. Remote testing kits are also well known and may include

means for sampling (as referred to above) and an assay designed to detect an analyte of interest. Such assays are well known and may include for example immunological or chemical based assays. Self performing assays (SPAs) are exemplary of an assay that may be included in a test kit. Generally, SPAs contain all reagents necessary for performing a chemical or immunological assay. These reagents are often times applied to a platform such as a bibulous strip or contained in a receptacle such as a tube. While all of the reagents are supplied with the SPA itself, the test sample is provided by the person being tested. Typically, the person being tested places the test sample on the platform or in the receptacle and waits for a short incubation time for a result. It should be understood that SPAs are merely exemplary of assays that may be contained in a test kit and that other assays are available and choices of which assay to employ are a matter of choice largely based upon nature of the sample and test required. Hence, the test kit will typically comprise (1) one or more collection or sampling instruments 12 (Figure 1) to assist in collecting a sample, and/or (2) an assay or receptacle for holding the sample, and, optionally, (3) a return envelope or the like into which a sample can be placed and sent to a testing facility (laboratory). Additionally, the test kit or element thereof can be provided with an indicator 11 (Figure 1) such as a: bar code, time marker, date marker, clock, magnetic time and date stamp, temperature indicator or thermometer, blood pressure gauge or monitor, fingerprint pad or marker, label, identification number, name, lettering, code, graphics or other indicia of the person using the kit, the time it was used, the location where it was bought or used, the purpose of the kit, or like indicia.

At the remote location site, the patient can open the test kit, collect a sample with the sample collection instrument 12 (Figure 1) and place the sample in the collection device of the test kit, preferably without a medical doctor, medical technician or nurse. The sample can be, for example, urine, saliva, breath, hair, fingernails, buccal cells, oral fluids, stool, skin, sweat, nasal fluids, mucous, semen, vaginal secretions, blood, ocular fluids, eye swabs, or ear wax.

The collected sample can be sent by delivery service 13 (Figure 1), such as by express delivery, courier service or mail, to a designated site equipped with appropriate instruments, assays, and/or personnel to test the sample and/or interpret the results of the sample or assay. In cases where the contents of a used test kit require further testing as in the case where, for example, a urine or blood sample is taken and sent to a remote site, the sample can be tested for an analyte, medical characteristic, condition, disease state, medical environmental hazard, or disease, such as: digoxin, glycated hemoglobin, albumin, microalbumin, heart disease, coumadin therapy, digitalis, therapeutic drug monitoring, mental health, depression, cancer, carcinoembryonic antigen (CEA), prostate specific antigen (PSA), prostate cancer, hormone replacement therapy (HRT), breast cancer, osteoporosis,

estrogen therapy monitoring, estrogen levels, epilepsy, anticonvulsant drug, kidney problems or failure, diabetes, BUN, creatinine, antibiotic therapy monitoring, acute C-reactive protein (CRP), strep. A, strep. B, influenza, urinary tract infection (UTI), sexually transmitted diseases (STD), chlamydia, gonorrhea, syphilis, infectious diseases, human immunodeficiency virus (HIV), HIV viral load, acquired immune deficiency syndrome (AIDS), herpes simplex virus, hepatitis, cognitive function, Alzheimer disease progression, fertility monitoring, LH, FSH, progesterone, estrogen, testosterone, E3, hCG, nutritional status, nutritional assessment, environmental hazard screening, environmental contaminants and pollutants, heavy metal, mercury, lead, asbestos, encephalitis, *E. coli*, glucose, glycated proteins, ketones, steroids, cancer markers, drugs of abuse, toxicology, vitamins, vitamin deficiency, specific gravity, smoking problems, lung cancer, cotinine, carbon dioxide, asthma, lung capacity, tuberculosis, pneumonia, blood alcohol, gastrointestinal diseases, *H. pylori*, Ebola virus, colon cancer, colon cysts, colon polyps, occult blood, inflammatory bowel disease, fiber level, allergies, cystic fibrosis, bacteria, infectious organisms, dental assessments, tooth decay, saliva acidity, yeast infections, yeast levels, genetic testing, forensics, toe fungus, athlete's foot, pink eye, blood pressure, cholesterol level, varicella zoster virus (herpes zoster), cytomegalovirus, Epstein barr, papilloma virus, cellulitus, staphylococci, streptococci, mycobacteria, adenoviruses, encephalitis, meningitis, arbovirus, arenavirus, anaerobic bacilli, picornavirus, coronavirus, 20 synsyrialvirus, and the like.

The test equipment or diagnostic equipment 14 (Figure 1) employed to test a sample at, for example, a laboratory are well known and a matter of choice depending upon the sample and test desired. Such instruments include but are not limited to immunodiagnostic analyzers, immunoassay systems, hematology analyzers, blood screening instruments, blood analyzers, chemistry instruments, chromatography instruments, urine analyzers, semen analyzers, hair analyzers, tissue and pore analyzer,s drug monitors, microbiology analyzers, and SPAs. Diagnostic equipment available from Abbott Laboratories in Abbott Park, Illinois USA is well suited for such analysis and examples of such instrumentation includes the AxSYM® brand high-volume immunoassay testing system, the IMx® brand immunoassay testing system, the TDx® brand and TDxFLx® brand therapeutic drug monitoring systems, LCx® systems for analyte detection based upon nucleic acid probe technology, the Cell-Dyn® 3000 brand and Cell-Dyn® 3500 brand automated hematology analyzers, Spectrum brand clinical chemistry instruments, CCX™ brand clinical chemistry instrument, Vision® brand desk-top clinical chemistry analyzer, and TestPack® brand and TestPack Plus® brand self-performing tests for pregnancy, strep throat and chlamydia.

The test results obtained from testing of the sample may be, for example, test data, information answers, chemical reactions, chemical analysis, color change, or visual

appearance. Test results and/or any interpretation thereof and desirably medical profile 15 (Figure 1) of the patient are electronically inputted or scanned and fed into a central processing unit (CPU) with an electronic inputting device 16 (Figure 1) such as a: keyboard, optical scanner, telephone, modem, cellular phone, internet link, world wide web connection, cable, phone line, computer, or touch screen display. The CPU 18 (Figure 1) can be for example, a microprocessor, computer, computer system, computer network, data processing center and the like. The medical profile can comprise electronic patient data and files about, for example, the patient's age, sex, height, weight, current and/or past medical history, physician, spouse, sex partners, parents, and children.

The CPU can access at least one data base 19 (Figure 1), using, for example, a modem 20, and can compare the analysis of or actual test results with the medical profile and a data base(s) in order to generate an electronic diagnosis and recommendation (recommended course of action), such as: medical treatment, medicine, dosage, prescription drugs, over-the-counter drugs, nutritional supplements, treatment regimens, exercise, diet, and compliance reminders. The data base(s) can comprise comprehensive electronic (computerized) information about: chronic diseases, infectious diseases, environmental diseases, general health information, fertility, nutrition, medical treatment, prescription drugs, over-the-counter drugs, medicine, care maps, treatment guidelines, medical texts, product information, insurance guidelines, DNA data, sequence listings, fingerprint information, statistical probability tables, patient information and the like.

The CPU's electronic diagnosis and recommendation can be transmitted by a transmitter 21 (Figure 1) to medical personnel 22 (Figure 1), such as a physician or health care provider who can personally or through the assistance of others input their approval or changes via an electronic inputting updating device 24 (Figure 1) into the CPU at step 26 (Figure 1) to provide feedback to the patient. The CPU can then contact the patient, health care professional or other qualified person, to notify the person that an approved or changed diagnosis and recommendation has been entered into the CPU. The CPU can contact the appropriate person using transmitters 28-30 (Figure 1) such as a modem 28 to send, for example, e-mail, a recorded telephone message or a facsimile. In order to assure the confidentiality and security of the user, the CPU will verify that the person seeking to access the approved or changed diagnosis and recommendation is in fact an appropriate person, before transmitting to the approved or changed diagnosis and recommendation resulting from the sample collection and testing. Desirably, confirmation of the approved or changed diagnosis and recommendation are printed on a printer 32 (Figure 1) connected to the CPU and sent by facsimile, mail, express delivery, or courier to the patient 34 (Figure 1) and physician or health care provider at step 36 (Figure 1).

In some circumstances and for some types of tests, it may be desirable that the patient self-test 38 (Figure 1) the sample at the patient's home or other remote location site in accordance with instructions in the test kit, instead of sending the sample to the laboratory to be tested. For self-tests, the patient or others can input and feed the test results into the CPU, for interpretation and analysis, although it is preferred that the patient first contact a designated counselor or advisor 40 (Figure 1), or the patient's physician or health care provider, with a transmitting device 41, such as with a telephone, internet or e-mail (electronic mail) etc. to discuss the test and test procedure. The counselor or others can input and feed the test results into the CPU with an inputting device 42 (Figure 1), similar to those described above.

The patient can obtain and acquire the test kit by purchasing the test kit from a retailer 44 (Figure 1) such as a: pharmacy, store, mail order supply house, or from an approved company advertised on television, radio, newspaper, magazine, catalog, internet or a web site. The test kit can also be delivered to a patient identified, designated and selected by the CPU at the request and expense of an organization 46 (Figure 1) such as: an insurance company, an integrated health care provider, a managed care provider, a health maintenance organization (HMO), a medical group, a public health agency, a Ministry of Health, the Center for Disease Control, an environmental agency, or a hospital. The patient or an employee of the organization can collect the sample, test the sample, input and feed the test results into the CPU, or can have the sample sent to and tested by a laboratory. The test results can be automatically tracked by the CPU for the organization and the electronic computerized diagnosis and recommendation (recommended course of action) can be transmitted to the organization by a transmitter 47 (Figure 1) by telephone via a modem, by electronic mail (e-mail), by facsimile, express delivery, or mail. The CPU can also transmit recommended drug prescriptions via a transmitter 48 to a designated pharmacy 50 (Figure 1).

The CPU and automatic test reporting process can further assist patients in selecting a health care provider such as a: managed care organization, medical group, hospital, physician, etc. In this regard, the CPU can electronically compare the financial criteria and location of the patient with: a list of available health care providers for the patient, the health status and medical recommendations for the patient and the patient's family, and health care programs available from the employers of the patient's family, before identifying and recommending a health care provider.

The automatic test reporting process and system can also be useful for electronically administering non-invasive tests 60 (Figure 2) to a patient, customer or student, such as: hearing tests, blood pressure, pulse, electroencephalograph (EEG), electrocardiograph (EKG), respiration rate and function, vision tests, reading tests, and cognitive function

tests, such as for monitoring the progress of Alzheimer's disease. The tests can be administered in the patient's home or other remote location site without the physical presence of a physician, optometrist, optomologist, audiologist, nurse or medical technician. For these tests, the test kit can take the form of an electronic auditory (hearing) test which can be transmitted by an auditory transmitter 62 (Figure 2) or carrier, such as by telephone, modem, cable, internet, world wide web, television, radio, etc. and/or a visual test which can be transmitted by a visual transmitter 64, such as by cable, satellite or other signaling system to a receiver 66 (Figure 2) such as: a monitor, computer display screen, flat panel display, light emitting diode (LED) screen, active matrix display screen, passive matrix display screen, liquid crystal display, or television. The test answers and results can be inputted into the CPU 68 (Figure 2) by the person taking the test with the same or a similar transmitter or inputting device 70 (Figure 2), such as a: telephone, modem, computer keyboard, internet, or test controller. The patient's medical profile 72 can also be inputted into the CPU. The CPU analyzes the test results; accesses a data base(s) 74 (Figure 2) containing electronic information about hearing tests, vision tests, reading tests, cognitive function, Alzheimer's disease, eye care, eye diseases, optical lenses, eyeglasses, contact lenses, ear care, hearing aids, ear drums, ear diseases, etc.; electronically compares the test results with the patient's medical profile and data base; and generates an electronic diagnosis and recommendation (recommended course of action) for the patient. Before being sent to the patient, the electronic diagnosis and recommendation can be transmitted by transmitter 76 (Figure 2), similar to those previously described, to medical personnel 78, such as: the patient's physician; optomologist; optometrist, audiologist; eye, ear and nose doctor; or health care provider; who can input their approval or changes of the electronic diagnosis and recommendation with an electronic updating inputting device 80, similar to those previously described, into the CPU at stage 82 to provide feedback for the patient 84. The diagnosis and recommendation can include: medical treatment, prescriptions for eyeglasses, contact lenses or hearing aids, prescription drugs, over-the-counter drugs, etc. The CPU can then transmit the approved or changed diagnosis and recommendation, via a carrier or transmitter 86 (similar to those previously described) to the patient.

For invasive testing, the process and system include a remote sample collection and testing device with automated test results tracking, automated result reporting to the physician or health care provider, and automated call back from the physician or health care provider to the patient with the test results, as well as interpretation and medication or treatment regimen changes. The automated system (CPU) can call the patient's pharmacy with prescription changes as recommended by physician or health care provider. To further assist patients with compliance to medication and treatment regimens in everyday living, the process and system can contact chronic disease patients on a regular schedule in order to

prompt patients to take medications, exercise, diet or follow any other area of disease treatment regimen. For example, at regular intervals, the CPU can contact a patient wearing a beeper to remind them to take their medication. Chronic diseases to which this invention apply include, but are not limited to: diabetes (i.e., glycated hemoglobin, microalbumin), heart disease (i.e. coumadin therapy, digoxin monitoring), therapeutic drug monitoring, transplant drug monitoring, mental health (i.e., anticonvulsant drug monitoring), kidney failure (BUN, creatinine, albumin, antibiotic therapy monitoring).

Chronic disease patients can acquire a remote sample collection and testing device for an analyte identified to monitor the status of their disease progression or their compliance with medication and treatment regimens. Such sample collection and testing kits can be acquired via: purchase in a retail outlet such as a pharmacy, issuance from an insurance company, issuance from a managed care provider, or issuance from any channel involved in the patient's health care. The remote sample collection and test kits preferably contains all materials required to obtain the necessary sample type, to send the sample to a laboratory, or to perform the necessary test on the sample directly at home. Each remote sample collection and testing kit can contain a bar-coded, unique, personal identification number (PIN) for the patient. After the patient acquires a remote sample collection and testing kit, the patient collects samples for non-invasive testing directly. Direct tests or home testing can be interpreted by the consumer or by a designated advisor. A decision to see a health care provider is made by the consumer based on test results. Patient results are sent to the system and tracked by a unique bar-coded ID. This procedure can be used to update the patient database and patient history regardless of the decision to see a health care provider. The process and system then transmits the patient test results with the patient history and recommends changes to the health care provider, if necessary. The physician or health care provider can approve or change recommendations. The process and system automatically calls the patient with the doctor's recommendation. The process and system can automatically call the patient's pharmacy with medication or prescription changes approved by the health care provider. The process and system can further automatically schedule visits to the health care provider if necessary.

In the case of samples sent to a laboratory, the laboratory will test the sample using appropriate professional laboratory tests. The laboratory will track the patient sample via the patient's unique, bar-coded remote sample collection and/or test kit identification (ID) number. Patient test results will be reported automatically through computer link, wireless transmission, or other secured, available technology to the patient's identified physician or health care provider. Physicians or providers will receive the patient's history, current test results, and any recommended changes in the patient's medication or treatment regimen. The physician or health care provider will approve or change the recommendations of the

CPU. The process and system will then automatically call the patient back with the patient's result report and recommended medication or treatment regimen changes. In order to assure and guarantee that the patient receives the call back, the following procedures can be followed: 1) the patient will punch in or speak an identification number into the phone or internet or other computer link upon receiving the automatic call back. If the correct patient ID is given, the patient will access the test results and physician feedback. If the patient ID is incorrect, the process and system will hang up and call again later. Once the patient call back is cleared from the process and system, written confirmed delivery of the results will be sent via mail to the patient and the physician or health care provider. 2) Upon receiving the call back, the patient is prompted to call a telephone number, such as an 800#, punch in an ID, to receive the test results. Written confirmed delivery of results will be sent via mail or express delivery to the patient and the doctor or health care provider. The system can also automatically call the patient's pharmacy with the necessary medication and prescription changes. Patient records can be maintained in the computer system (CPU) for the patient's life time or until the patient requests that the patient's records be expunged. In the case of direct testing of samples at home, test results may be coded. The results can also be masked, requiring the patient to contact a designated advisor for test result interpretation. When a patient contacts an advisor, via phone, internet, wireless system, or other secured communication technology, the patient's test results can be inputted into the CPU by the advisor and can be tracked based upon the unique, bar-coded remote sample collection and test kit ID number. The advisor can interpret the patient's results based upon a pattern or number code appearing on the direct test device. Patients can be advised of the test results by phone from the advisor or told to wait for a physician or health care provider response. Patient results will be reported automatically through computer link, wireless transmission, or other secured, available technology to the patient's identified physician or health care provider. Physicians or providers will receive from the CPU the patient's history, current test result, and any recommended changes in the patient's medication or treatment regimen. The physician or health care provider will approve or change the computer's recommendations and have the approval or changes inputted into the CPU. The process and system will then automatically call the patient back with the patient's test results, as well as recommended medication or treatment regimen changes. Guarantee that the patient receives the call back will be generated in one of several ways discussed previously.

Assurance that a specific patient performed the sample collection procedure on themselves can be provided via various time and identification verification methods, such as with a magnetic-tape date-stamp built into the collection device to record the exact date and time of testing, or a date and time clock built into the test that stops when patient sample is

applied, a sample temperature verifying mechanism, or a patient fingerprint applied with the sample.

Upon entering or inputting test result information, the CPU can analyze, compare, calculate or otherwise manipulate the input and, based upon this manipulation, select, for example, a recommended course of action, suggest a health insurance option, contact various professional personnel or agencies, and/or contact the patient.

For example, depending upon whether or not a patient fits a particular profile, the process and system can contact a provider and direct the provider to send a remote sample collection or test kit to appropriate chronic disease patients on a schedule which may be determined by a managed care organization or other health care provider. While chronic disease patients may be on a schedule determined by a health care provider, it is the system provided herein that maintains this schedule by insuring that an appropriate kit is provided at the designated times. The system can perform this function through the use of look up tables to match a patient with an appropriate test kit. Additionally, time schedules can be maintained by the present system by referencing an internal clock, well known to those skilled in the art, to determine when to contact a provider.

The system also provides patient result tracking and result reporting to various health care providers, as well as the patient. For example, upon entry of a test result and the type of test that was performed, the CPU can consult commonly used look up tables to determine sites that need to be contacted based upon the inputted information. In a simple case, the CPU may consult a look up table to match a patient with her physician who is then contacted with the test result. According to another embodiment, the patient's test results can be reported to the physician and health care provider along with the patient's medical history and a listing of current medications after accessing and pulling such information from a data base containing this information. Additionally, the CPU can deliver treatment recommendations based upon a statistical analysis of the patients history and previous treatments, as they relate to outcomes from similarly situated patients of like demographic information. The CPU can make such recommendations through the use of look up tables containing a listing of various treatments and an outcomes database comprising information about other similarly situated patients who previously have been treated with varying degrees of success.

In cases where the CPU provides a treatment recommendation to a physician or other health care provider, the physician or health care provider may have the opportunity to access the CPU and approve or modify the CPU's recommendation. Upon receipt of an approval or modification signal, the CPU recognizes that such a signal has been received which then permits the CPU to take further actions. For example, in cases where a medication is prescribed, a pharmacy can be contacted with the appropriate prescription.

Additionally, the patient can be notified that a medication has been prescribed and is available at a particular pharmacy. The patients outcome of the approved or modified treatment recommendation can be added to the outcome database so that the database contains the most current information about various treatments for future recommendations to patients of like condition and demographic background.

The process and system can also provide a remote sample collection and testing device for analytes which monitor health status. The process and system includes automated consumer results tracking, consumer counseling, test interpretation and referral, as well as automated result reporting to physician as requested by the patients. This process includes, but is not limited to, tests such as: acute CRP, Strep A. Strep B, influenza tests, UTI, sexually transmitted diseases, e.g., chlamydia, gonorrhea, etc., infectious diseases e.g., hepatitis, etc.

Patients can acquire a remote sample collection and testing device for an analyte identified to monitor their health status. For direct testing of samples at home, results may appear directly on the testing platform, allowing the consumer to interpret the test on their own and offering the alternative to call a manufacturer's designated advisor for result interpretation and referral information. Alternately, results may be coded or masked, requiring the patient to contact a designated advisor for test result interpretation.

When consumers contact an advisor, via phone, internet, wireless system, or other secured communication technology, the consumer's test result can be tracked with, for example, a unique bar-coded remote sample collection and test kit ID number. Advisors can interpret the patient's results based upon a pattern or number code appearing on the direct test device. The patients can be advised of their test results by the advisor and recommended to visit a health care provider, if necessary. The patient can also enter the test results into the CPU. The CPU determines and analyzes the test results and reports the test results and its analysis automatically through computer link, wireless transmission, or other secured, available technology to the patient's identified physician or health care provider. Physicians or providers will receive the patient's history, current test results, test result-interpretation, and a recommended diagnosis and treatment plan generated by the CPU. The physician or health care provider can approve or change the computer's recommendations. Upon confirmation, the process and system will then automatically call the patient back with the test results, physician's recommendations, and any recommended medication or treatment regimen changes, as described previously.

The process and system can identify patients for testing each month or on a regular basis. The system can initiate posting of collection and test kit to patients. The process and system can automatically send remote sample collection and testing device kits for specific analytes to appropriate patients on a schedule determined by the Ministry of Health, health

agency or other health care provider according to group care maps or treatment guidelines. The patient's results and physician treatment decision will be added to the outcomes database to keep current the statistical analysis of patient treatment and outcomes. Areas to which this process apply include, but are not limited to: chronic diseases, such as: diabetes (i.e., glycated hemoglobin, microalbumin), heart disease (i.e. coumadin therapy, digoxin monitoring), therapeutic drug monitoring, transplant drug monitoring, mental health (e.g., depression), cancer (e.g., prostate cancer, breast cancer), osteoporosis (i.e. estrogen therapy monitoring), epilepsy (i.e. anticonvulsant drug monitoring), general health monitoring (e.g., general chemistry panels and CBCs), fertility monitoring (LH, FSH, progesterone, estrogen, testosterone, etc), STD testing (chlamydia, gonorrhea, etc), infectious disease testing and monitoring (e.g., HIV viral load, hepatitis, etc) and nutritional status monitoring. The system can down load patient data to the database for updating.

The automated process also can provide vision monitoring, hearing loss testing and cognitive function testing to track the progress of Alzheimer's disease. In the case of non-invasive tests, such as vision, hearing or cognitive function, the consumers contact or are contacted by a testing center via phone, internet, wireless system, or other secured communication technology. The consumer will be assigned a unique ID number. Desired tests will then be administered via telephone (hearing or cognitive function test), internet (vision or cognitive function test), wireless system (hearing, vision, or cognitive function test), or other secured communication technology appropriate for the necessary test. The CPU can compare the patient's responses to the tests with a database of test answers to calculate test results. Test results will be reported to the consumer or others as described above. The consumer can be advised about the test results by an advisor and recommended to visit a health care provider, if necessary. The computer system (CPU) can schedule a physician office visit, if necessary, based upon test results above or below a designated baseline value. Patient results can be reported through computer link, wireless transmission, or other secured, available technology to the patient's identified physician optometrist, optomologist, audiologist, or health care provider.

The process and system are also useful to monitor elderly patients. The computer system (CPU) can track a patient's results over time and flag results as the results begin to indicate a change in the patient's status as the patient ages. For example, upon determining that a patient is above a certain baseline level of an analyte being monitored, the CPU alerts a patient and/or the patient's physician, if the test results of the medical condition being monitored, reach a predetermined level. This will allow patients and physicians to take proactive measures to help prevent catastrophic health care needs in the future. Test sample collection, analysis and reporting are similar to the described above.

The process and system can also be helpful to an employee in selecting a health care plan. The process and system can include a remote sample collection and testing device, in conjunction with a patient access to a computer system that utilizes relational databases to recommend actions. The computer system can use databases to access historical health information on the employee and or the employee's family members, store test results indicating the employee's current health status, access statistically significant health information on demographically similar individuals, access a house-call on a disk-type program that makes medical recommendations based upon test results and patient history, and put all this information into an algorithm or software program that contrasts health care insurance and programs available in comparison to the employee's health status, financial status, and history. Once a test result has been obtained, the computer system can analyze the test results in relation to the patient's medical history, current clinical vital signs, statistically significant health data from individuals of like demographics, and medical decision software. The computer system (CPU) can use an algorithm or software program to compare and contrast salient parameters of the various health care programs (i.e., deductibles, maximum lifetime coverage, prescription drug benefits, etc) and make a recommendation to the employee on which health care plan the employee should select.

The process and system can also feature a remote sample collection and testing device and provide computerized data handling and automated community notification. The process and system can provide automated patient result tracking and automated result reporting to public health facilities and the Center for Disease Control (CDC). The patient results can be reported to the public health with statistical analysis of disease prevalence in that facility and in the state as a whole. Patients can contact the system for test results, interpretation, counseling and referral recommendations. The automated process and system can schedule referral visits for the patient, as desired, if the test results exceed a selected range. The automated system can call patient's exposed partners as required by law or requested by the patient. The patient's results can be added to the CDC database to keep current the statistical analysis of disease prevalence. Areas to which the process and system can apply include, but are not limited to: mental health (e.g., depression), cancer (e.g., prostate cancer, breast cancer), osteoporosis (i.e. estrogen therapy monitoring), epilepsy (i.e. anticonvulsant drug monitoring) general health monitoring (i.e. general chemistry panels and CBCs), fertility monitoring (LH, FSH, progesterone, estrogen, testosterone, etc), sexually transmitted disease (STD) testing (e.g., chlamydia, gonorrhea, syphilis, etc), infectious disease testing and monitoring (e.g., HIV, hepatitis, etc), nutritional status monitoring, environmental hazard screening (e.g., pollution, asbestos, lead), environmental borne disease testing (e.g., encephalitis, E. coli), and cardiovascular health (e.g. blood pressure, pulse, EEG, EKG).

For infectious disease diagnosis, treatment, counseling, tracking and reporting the patient can acquire a remote collection and testing kit from public health. The patient, collects the sample and posts or otherwise sends the sample or tests directly. The samples are tested by a laboratory. Self-tests can be interpreted by the patient or an advisor (consultant). The patient results can be sent to public health facility and to the Center for Disease Control (CDC). The patient results can be tracked by a unique bar-coded ID. The public health facility prevalence statistics can be calculated by the CPU to provide overall data. The patient contacts the system for results, counseling and referral, as described previously. The process and system can schedule referral appointment on request.

Environmentally borne disease investigation and reporting are typically initiated by a report of the disease outbreak to the Public Health. Public health scientists visit the suspected site, collect samples with remote sample and testing kits and gather names of exposed individuals. The samples are tested in a laboratory or direct tested on site. Test results are entered into the CPU as previously described. The CPU tracks and analyzes the test results. The CPU can also compare the test results with databases concerning the test, environmental borne diseases, and treatments to determine if the patient has an environmental borne disease and, if so, determine an appropriate treatment. The test results can be collated and sent to public health facility and the CDC automatically by the CPU. The process and system can automatically notify exposed individuals and send them test kits. The exposed individual can collect and send the sample to the indicated laboratory as described previously. The samples are tested in the laboratory and the test results can be reported by the process and system to the public health facility, individual and the CDC. The process and system can also perform needed statistical analysis of data and reports for public health and CDC.

For environmental hazard screening and abatement, the automated process and system can provide analysis of population, flagging high risk areas. The public health can distribute remote sample and test kits to high risk targets. The targets (persons at risk) collect samples and send the sample to an indicated laboratory for testing. The test results are entered into the CPU as described previously. The CPU tracks and analyzes the test results. The CPU can also compare the test results with databases concerning the test, environmental hazards and treatment, to determine if the patient has a medical condition attributable to the environmental hazard and, if so, identify an appropriate treatment. The process and system can report the test results to public health and the CDC. The process and system can automatically notify positive individuals with public health approval. Positive patients are treated, to the extent possible. Suspect environments should be abated. The process and system can prompt the patient's health care provider or health agency to re-test the patients.

To further assist patients with compliance to medication and treatment regimens in everyday living, the process and system can be programmed to automatically call chronic disease patients on a regular schedule to prompt patients to take medications, exercise, diet or follow any other area of disease treatment regimen.

5 Although embodiments of this invention have been shown and described, it is to be understood that various modifications and substitutions of process steps, test procedures, equipment, instruments, devices and test kits, can be made by those skilled in the art without departing from the novel spirit and scope of this invention.

What is claimed is:

1. An automatic test reporting process, comprising the steps of:
inputting the results of at least one test into a central processing unit; and
automatically contacting a person selected by said central processing unit with
said test results.
2. An automatic test reporting process in accordance with claim 1 wherein said
person or agency comprises at least one member selected from the group consisting of: a
public health official, a health department employee, an official of the Center for Disease
Control, an environmentalist, physician, a staff member of a hospital, trauma center
5 personnel, a health care provider, a managed care provider, a medical doctor, nurse, a
dentist, an insurance representative, a patient, a customer, a student, a pharmacist, a
medical supply house, a nutritionist, a hygienist, psychiatrist, psychologist, optometrist,
optomologist, and audiologist.
3. An automatic test reporting process in accordance with claim 1 wherein said test
results are reported to said person selected by said central processing unit based upon test
result information.
4. An automatic test reporting process in accordance with claim 1 wherein said
central processing unit is selected from the group consisting of a: microprocessor,
computer, a computer system, computer network, computer chip, circuit board, control
board, programmable controller, logic controller, mainframe, and data processing center.
5. An automatic test reporting process in accordance with claim 1 wherein said test
results are electrically inputted with at least one device selected from the group consisting
of: a keyboard, optical scanner, a telephone, a modem, a cellular phone, an internet
connection, world wide web connection, a computer, a touch screen display, and a data
processing center.
6. An automatic test reporting process in accordance with claim 1 wherein said
contacting includes using at least one device selected from the group consisting of: a
transmitter, a beeper, a receiver, a telephone, a modem, a cellular phone, a cable, an
internet carrier, a world wide web link, a television, a closed circuit monitor, a computer, a
display screen, a telephone answering machine, facsimile machine, and a printer.

7. An automatic test reporting process in accordance with claim 1 wherein said automatic contacting includes verifying the identification of the person before providing the person with the test results.

8. An automatic test reporting process in accordance with claim 1 including:

administering a non-invasive test selected by said central processing unit from the group consisting of a hearing test, a vision test, reading test, and a cognitive function test;

5 electronically transmitting said test in proximity to the person being tested to a receiver selected from the group consisting of a television, monitor, display screen, computer screen, flat panel display, LED screen, active matrix display screen, passive matrix display screen, liquid crystal display, internet, web site, telephone and cellular phone; and

10 automatically contacting the person or a health careprovider with a recommendation selected from the group consisting of medical treatment, prescription drugs, over-the-counter drugs, medicine, and prescriptions for eyeglasses, contact lenses, or hearing aids.

9. An automatic test reporting process in accordance with claim 1 wherein:

a sample is collected by a member selected from the group consisting of a patient, a customer, an assistant, a sample collector, and a public health official; and
said sample is tested to obtain said test results.

10. An automatic test reporting process in accordance with claim 9 wherein said sample is tested by said member.

11. An automatic test reporting process in accordance with claim 9 wherein said sample is tested by a laboratory.

12. An automatic test reporting process in accordance with claim 9 wherein said sample is selected from the group consisting of: urine, saliva, breath, hair, fingernails, fingerprints, buccal cells, oral fluids, stool, skin, sweat, nasal fluids, mucous, semen, vaginal secretions, blood, ocular fluids, eye swabs, and ear wax.

13. An automatic test reporting process, comprising the steps of:

collecting a sample at a site remote from a central processing unit;
testing said sample with a test kit to obtain test results;

5 inputting said test results into said central processing unit;

10 accessing at least one data base with said central processing unit, said data base comprising electronic and information selected from the group consisting of chronic diseases, infectious diseases, environmental diseases, general health information, fertility, nutrition, medical treatment, prescription drugs, over-the-counter drugs, medicine, care maps, treatment guidelines, medical texts, medical journals, product information, DNA data, sequence listings, and fingerprint information;

 electronically comparing said test results with said data base via said central processing unit;

 generating a recommended course of action with said central processing unit; and transmitting said recommended course of action.

14. An automatic test reporting process in accordance with claim 13 wherein said site is selected from the group consisting of a patient's home, place of business, store, or other location remote from a medical facility, hospital, trauma center and doctor's office.

15. An automatic test reporting process in accordance with claim 13 wherein;

5 a patient's profile is inputted into said central processing units and compared with said data base; and

 said patient's profile comprises data selected from the group consisting of a patient's age, sex, height, weight, medical history, current medication, physician, spouse, sex partners, parents, and children.

16. An automatic test reporting process in accordance with claim 13 wherein said recommended course of action comprises at least one recommendation selected from the group consisting of medical treatment, medicine, dosage, product identification, prescription drugs, over-the-counter drugs, nutritional supplements, treatment regimens, exercise, diet, insurance, hospital, health care provider, physician, managed care provider, and compliance reminder.

5 17. An automatic test reporting process in accordance with claim 13 wherein said sample is collected by a patient in the absence of a medical doctor, medical technician, and nurse.

18. An automatic test reporting process in accordance with claim 17 wherein said sample is tested by said patient.

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19. An automatic test reporting process in accordance with claim 18 wherein said patient contacts a counselor with said test results; and said counselor inputs said test results into said central processing unit.
20. An automatic test reporting process in accordance with claim 17 wherein:
said sample is tested by a laboratory;
said recommendation is transmitted to medical personnel selected from the group consisting of a physician or health care provider;
said medical personnel approving or changing said recommendation to update said recommendation; and
transmitting said updated recommendation to said patient.
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21. An automatic test reporting process in accordance with claim 20 including verifying the identification of the patient before said patient can access the updated information.
22. An automatic test reporting process in accordance with claim 20 wherein said updated information is printed and delivered to said patient and said medical personnel by mail, courier, facsimile or express delivery.
23. An automatic test reporting process in accordance with claim 13 wherein said test kit is obtained by purchasing said test kit from a facility selected from the group consisting of: a pharmacy; a store; a mail order supply house; or a company advertised on television, radio, newspaper, magazine, catalog, internet or a web site.
24. An automatic test reporting process in accordance with claim 13 wherein:
said patient is selected by said central processing unit at a request of an organization selected from the group consisting of: an insurance company, an integrated health care provider, a managed care provider, a health maintenance organization, a medical group, hospital, a public health agency, ministry of health, environmental agency, and Center for Disease Control; and
said test kit is delivered to said patient at the request and expense of said organization.
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25. An automatic test reporting process in accordance with claim 13 wherein:
said sample is collected by an employee of an organization selected from the group consisting of a public health agency, ministry of health, environmental agency, and Center for Disease Control;

5 said test kit is obtained and paid for by said organization;

said test results are automatically tracked by said central processing unit for said group; and

said test results and recommendations are transmitted to said organization.

26. An automatic test reporting process in accordance with claim 13 wherein said recommended course of action is transmitted by a carrier selected from the group consisting of: a phone, modem, cellular phone, facsimile, cable, internet, world wide web, global interconnected communications network, a satellite system, a computer, computer network, mail, express delivery, courier, keyboard, computer screen, flat panel display, monitor, and television.

5 27. An automatic test reporting process in accordance with claim 13 wherein said inputting comprises electrically inputting with at least one device selected from the group consisting of: a keyboard, telephone, modem, cellular phone, internet connection, world wide web connection, computer, and touch screen display.

28. An automatic test reporting process in accordance with claim 13 wherein said sample is selected from the group consisting of: urine, saliva, breath, hair, fingernails, buccal cells, oral fluids, stool, skin, sweat, nasal fluids, mucous, semen, vaginal secretions, blood, ocular fluids, eye swabs, and ear wax.

5 29. An automatic test reporting process in accordance with claim 13 wherein said central processing unit is selected from the group consisting of a: microprocessor, computer, a computer system, computer network, semiconductor chip, circuit board, control board, programmable controller, logic controller, mainframe, interconnected global communication network, satellite system, internet, world wide web, and data processing center.

30. An automatic test reporting process in accordance with claim 13 wherein said test kit includes an indicator selected from the group consisting of: a bar code, time marker, date marker, clock, magnetic time stamp, magnetic date stamp, temperature indicator,

thermometer, blood pressure gauge, blood pressure monitor, fingerprint pad, label, identification number, name, lettering, code, graphics and indicia.

31. An automatic test reporting process, comprising the steps of:

obtaining a test kit comprising a remote sample collection and testing kit with an indicator selected from the group consisting of a bar code, time marker, date marker, clock, magnetic time stamp, magnetic date stamp, temperature indicator, thermometer, blood pressure gauge, blood pressure monitor, fingerprint pad, label, identification number, name, lettering, code, graphics and indicia;

said test kit being obtained by or for a patient;

said test kit being brought to a remote location site selected from the group consisting of a patient's home, place of business, store, or other location remote from a medical facility, hospital, trauma center, and doctor's office;

said patient opening said test kit at said remote location site;

said patient collecting a sample at said remote location site in the absence of a medical doctor, medical technician and nurse;

said patient placing said sample in said test kit at said remote location site;

said sample being selected from the group consisting of urine, saliva, breath, hair, fingernails, fingerprints, buccal cells, oral fluids, stool, skin, sweat, nasal fluids, mucous, semen, vaginal secretions, blood, ocular fluids, eye swabs, and ear wax;

testing said sample for a medical characteristic comprising an analyte, disease state, disease, medical condition, or medical environmental hazard, said medical characteristic being selected from the group consisting of diabetes, glycated hemoglobin, microalbumin, heart disease, coumadin therapy, digoxin monitoring, therapeutic drug monitoring, mental health, depression, cancer, carcinoembryonic antigen, prostate specific antigen, prostate cancer, breast cancer, osteoporosis, estrogen therapy monitoring, epilepsy, anticonvulsant drug monitoring, kidney failure, BUN, creatinine, albumin, microalbumin, antibiotic therapy monitoring, acute c-reactive protein, strep A, strep B, influenza, urinary tract infection, sexually transmitted disease, chlamydia, gonorrhea, syphilis, infectious diseases, human immunodeficiency virus, HIV viral load, acquired immune deficiency syndrome (AIDS), herpes simplex virus, hepatitis, cognitive function, Alzheimer disease progression, fertility monitoring, LH, FSH, progesterone, E3, hCG, estrogen, testosterone, nutritional status, nutritional assessment, environmental hazard screening, environmental contaminants, heavy metal, mercury, lead, asbestos, encephalitis, E. coli, diabetes, glucose, glycated proteins, ketones, steroids, cancer markers, drug abuse, toxicology, vitamins, vitamin deficiency, dehydration, specific gravity, smoking, continine, carbon dioxide, asthma, lung cancer, lung capacity, tuberculosis, pneumonia,

- 35 halitosis, blood alcohol, gastrointestinal disease, H. Pylori, Ebola virus, colon cancer, colon cysts, occult blood, inflammatory bowel disease, fiber level, allergies, cystic fibrosis, bacteria, RSV, viruses, bacteria, infectious organisms, dental assessment, tooth decay, saliva acidity, yeast infections, yeast levels, genetic testing, forensics, toe fungus, athletes foot, pink eye, dandruff, lice, schelorsis, blood pressure, varicella zoster virus, cytomegalovirus, Epstein barr, papilloma virus, cellulitus, staphylococci, streptococci, mycobacteria, adenovirus, encephalitis, meningitis, arbovirus, arenavirus, anaerobic bacilli, picornavirus, coronavirus, synsyrialvirus, pregnancy, and cholesterol level;
- 40 obtaining results from said testing of said sample comprising test results selected from the group consisting of test data, information, answers, chemical reaction, chemical analysis, color change, and visual appearance;
- 45 electronically inputting said test results and a medical profile of said patient into a central processing unit with at least one device selected from the group consisting of a keyboard, optical scanner, telephone, modem, cellular phone, internet connection, world wide web connection, cable, phone line, computer, and touch screen display;
- 50 said medical profile comprising patient data selected from the group consisting of a patient's age, sex, height, weight, medical history, current medication, physician, spouse, sex partners, parents, and children;
- 55 said central processing unit being selected from the group consisting of a microprocessor or computer, computer system, computer network, semiconductor chip, circuit board, control board, programmable controller, logic controller, mainframe, interconnected global communications network, satellite system, internet network, world wide web network, and data processing center;
- 60 accessing at least one data base with said central processing unit, said data base comprising electronic information selected from the group consisting of chronic diseases, infectious diseases, environmental diseases, general health information, fertility, nutrition, medical treatment, prescription drugs, over-the-counter drugs medicine, care maps, treatment guidelines, medical tests, product information, DNA data, sequence listings, and fingerprint information;
- 65 electronically analyzing said test results;
- 65 said central processing unit electronically comparing said analysis of said test results with said medical profile and data base;
- 70 generating a diagnosis and recommendation with said central processing unit, said recommendation being selected from the group consisting of medical treatment, medicine, dosage, prescription drugs, over-the-counter drugs, nutritional supplements, treatment regimens, exercise, diet, and compliance reminder:

transmitting said diagnosis and recommendation to medical personnel selected from the group consisting of a physician or health care provider;

75 said medical personnel approving or changing said diagnosis and recommendation and inputting their approval or changes into said central processing unit to provide feedback for said patient;

signaling the patient to access the approved or changed diagnosis and recommendation, said signaling being selected from the group consisting of telephone, transmitting electronic mail, and notification;

80 verifying that a person seeking to access the approved or changed diagnosis and recommendation is said patient; and thereafter

transmitting to said patient and permitting said patient to access and retrieve said approved or changed diagnosis and recommendation resulting from said sample collection and testing.

32. An automatic test reporting process in accordance with claim 31 wherein said sample is tested by a laboratory.

33. An automatic test reporting process in accordance with claim 31 wherein said sample is tested by said patient.

34. An automatic test reporting process in accordance with claim 31 wherein said patient informs a counselor of said test results by telephone or electronic mail.

35. An automatic test reporting process in accordance with claim 31 wherein said test kit is obtained by purchasing said test kit from a facility selected from the group consisting of: a pharmacy; a store; a mail order supply house; or a company advertised on television, radio, newspaper, magazine, catalog, internet or a web site.

36. An automatic test reporting process in accordance with claim 31 wherein:

5 said patient is selected by said central processing unit at a request of an organization selected from the group consisting of: an insurance company, an integrated health care provider, a managed care provider, health maintenance organization, a medical group, a public health agency, ministry of health, and Center for Disease Control; and

 said test kit is delivered to said patient at the request and expense of said organization.

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37. An automatic test reporting process in accordance with claim 31 wherein said sample is collected with an instrument selected from the group consisting of a: swab, cotton, gauge, lance, tissue, nail clippers, scissors, cup, bottle, container, test tube, capillary tube, petri dish, condom, bag, glove, tape, blotter, paper, paperboard, cardboard, dermatological patches, eye dropper, pipettes, collector device, sample retriever, and medical instrument.

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38. An automatic test reporting process in accordance with claim 31 wherein said sample is tested with diagnostics equipment selected from the group consisting of an: immunodiagnostics analyzer, immunoassay system, hematology analyzer, blood screen instrument, blood analyzer, chemistry instrument, chromatograph, urine analyzer, semen analyzer, hair analyzer, tissue and pore analyzer, drug monitor, microbiology analyzer, diagnostics instrument, and diagnostic device.

39. An automatic test reporting process in accordance with claim 31 wherein said diagnosis and recommendation are transmitted by telephone or electronic mail.

40. An automatic test reporting process in accordance with claim 39 wherein:
said approved or changed diagnosis and recommendation are printed; and
said printed diagnosis and recommendation are sent for confirmation to said patient and medical personnel by facsimile, mail, express delivery, or courier.

41. An automatic test reporting system, comprising:
a kit having an instrument for collecting a sample at a remote location selected from the group consisting of a patient's home, place of business, store or other location remote from a medical facility, hospital trauma center and doctor's office;
5 diagnostic equipment for testing the sample to obtain test results;
a central processing unit;
a patient's electronic profile comprising electronic data selected from the group consisting of a patient's age, sex, height, weight, medical history, current medication, physician, spouse, sex partners, parents, and children;
10 a data base comprising electronic information selected from the group consisting of chronic diseases, infectious diseases, environmental diseases, general health information, fertility, nutrition, medical treatment, prescription drugs, over-the-counter drugs, medicine, care maps, treatment guidelines, medical tests, medical journals, product information, DNA data, sequence listings, and fingerprint information;

15 at least one inputting device for electronically inputting the patient's electronic profile and test results into said central process unit;

20 send control processing unit accessing said data base and comparing said test results, patient's electronic profile and test results, and said central processing unit generating a recommended course of action comprising at least one recommendation selected from the group consisting of medical treatment, medicine, dosage, product identification, prescription drugs, over-the-counter drugs, nutritional supplement treatment regimens, exercise, diet, insurance, hospital, health care provider, physician, managed care provider, and compliance reminder; and

at least one carrier for transmitting said recommended course of action.

42. An automatic test reporting system in accordance with claim 41 wherein said central processing unit is selected from the group consisting of a: microprocessor, computer, computer system, computer network, semiconductor chip, circuit board, control board, programmable controller, logic controller, mainframe, global communications network, satellite system, internet, world wide web, and data processing center.

43. An automatic test reporting system in accordance with claim 41 wherein said kit comprises a test kit with an indicator selected from the group consisting of a: bar code, time marker, date marker, clock, magnetic time stamp, magnetic date stamp, temperature indicator, thermometer, blood pressure gauge, blood pressure monitor, fingerprint pad, label, identification number, name, lettering, code, and indicia.

44. An automatic test reporting system in accordance with claim 41 wherein said inputting device is selected from the group consisting of a: keyboard, telephone, modem, cellular phone, internet connection, world wide web connection, and touch screen display.

45. An automatic test reporting system in accordance with claim 41 wherein said carrier is selected from the group consisting of a: phone, modem, cellular phone, facsimile, cable, internet, world wide web, global communications network, satellite system, computer network, keyboard, computer screen, flat panel display, monitor, television, and facsimile machine.

46. An automatic test reporting system in accordance with claim 41 including a printer for printing said recommended course of action.

47. An automatic test reporting system in accordance with claim 43 wherein:
said carrier includes a first carrier for transmitting said recommended course of
action to medical personal to approve or change said recommendation, said medical
personnel selected from the group consisting of a physician or a health care provider;

5 said inputting device includes an updating device for inputting the approved or
changed recommendation to said central processing unit;

said carrier includes a second carrier for transmitting the approved or change
recommendation to a patient after verification of the patient's identity; and

said first carrier being the same or different than said second carrier.

48. An automatic test reporting system in accordance with claim 41 wherein said
sample is selected from the group consisting of: urine, saliva, breath, hair, fingernails,
buccal, cells, oral fluids, stool, skin, sweat, nasal fluids, mucous, semen, vaginal
secrections, blood, ocular fluids, eye swabs, and wax.

10 49. An automatic testing reporting system in accordance with claim 48 wherein said
instrument for collecting said sample comprises a sample collector selected from the group
consisting of a: swab, cotton, gauge, lance, tissue, nail clippers, scissors, cup, bottle,
5 container, test tube, capillary tube, petri dish, condom, bag, glove, tape, blotter, paper,
paperboard, cardboard, dermatological patches, eye dropper, pipettes, collector device,
sample retriever, and medical instrument.

50. An automatic testing reporting system in accordance with claim 48 wherein said
diagnostic equipment is selected from the group consisting of an: immunodiagnostics
analyzer, immunoassay system, hematology analyzer, blood screen instrument, blood
analyzer, chemistry instrument, chromatograph, urine analyzer, semen analyzer, hair
5 analyzer, tissue and pore analyzer, drug monitor, microbiology analyzer, diagnostics
instrument, and diagnostics device.

51. An automatic test reporting system comprising:
a central processing unit for electronically administering a non-invasive test
selected from the group consisting of a hearing test, vision test, reading test, blood
pressure, pulse, EEG, EKG, respiration rate, respiratory function and a cognitive function
test;
a receiver positioned in proximity to the person being tested at a location remote
from said central processing unit, said receiver being selected from the group consisting of
a television, monitor, display screen, computer screen, flat panel display, LED screen,

active matrix display screen, passive matrix display screen, liquid crystal display, internet, web site, telephone, and cellular phone;

10 at least one transmitter operatively associated with said central processing unit and said receiver for

transmitting said non-invasive test from said central processing unit to said receiver,

15 transmitting responses to said test from said receiver to said central processing unit, and

transmitting a recommendation from said central processing unit to said receiver;

20 at least one data base comprising electronic information selected from the group consisting of hearing, vision, color blindness, reading, cognitive function, Alzheimer disease, optical medical information, eye diseases, ear diseases, medical treatment, prescription drugs, over-the-counter drugs, medicine, care maps, treatment guidelines, medical tests, medical journals, optical lenses, eyeglasses, eyewear, and hearing aids;

25 a modem connected to said central process unit for accessing said data base; and

said central processing unit comparing said responses to said data base and generating said recommendation, and said recommendation being selected from the group consisting of medical treatment, prescription drugs, over-the-counter drugs, medicine, and prescriptions for eyeglasses, contact lenses, or hearing aids.

52. An automatic test reporting system in accordance with claim 51 wherein said central processing unit is selected from the group consisting of a: microprocessor, computer, computer system, computer network, semiconductor chip, circuit board, control board, programmable controller, logic controller, mainframe, global communications network, satellite system, internet, world wide web, and data processing center.

53. An automatic test reporting system in accordance with claim 51 including a printer operatively connected to said central processing unit for printing said recommendation.

54. An automatic test reporting system in accordance with claim 51 wherein said transmitter is selected from the group consisting of: a phone line, cable, internet, world wide web, global communications network, satellite system, radio frequency transmitter, a cellular transmitter, computer link, and a facsimile machine.

55. An automatic test reporting system in accordance with claim 51 wherein said recommendation comprises electronic mail (e-mail).

56. An automatic test reporting system, comprising:

5 a test kit comprising a remote sample collection and testing kit with an indicator selected from the group consisting of a bar code, time marker, date marker, clock, magnetic time stamp, magnetic date stamp, temperature indicator, thermometer, blood pressure gauge, blood pressure monitor, fingerprint pad, label, identification number, name, lettering, code, graphics and indicia;

10 said test kit being obtained by or for a patient, said test kit being brought to a remote location site selected from the group consisting of a patient's home, place of business, store, or other location remote from a medical facility, hospital, trauma center, and doctor's office; said patient opening said test kit and collecting a sample for placement in said test kit at said remote location site in the absence of a medical doctor, medical technician and nurse;

15 said sample being selected from the group consisting of urine, saliva, breath, hair, fingernails, fingerprints, buccal cells, oral fluids, stool, skin, sweat, nasal fluids, mucous, semen, vaginal secretions, blood, ocular fluids, eye swabs, and ear wax;

20 test equipment for testing said sample for a medical characteristic comprising an analyte, disease state, disease, medical condition, or medical environmental hazard, said medical characteristic being selected from the group consisting of diabetes, glycated hemoglobin, hormone replacement therapy, microalbumin, heart disease, digitalis, coumadin therapy, digoxin monitoring, therapeutic drug monitoring, mental health, depression, cancer, carcinoembryonic antigen, prostate specific antigen, prostrate cancer, breast cancer, osteoporosis, estrogen therapy monitoring, epilepsy, anticonvulsant drug monitoring, kidney failure, BUN, creatinine, albumin, microalbumin, antibiotic therapy monitoring, acute c-reactive protein, strep A, strep B, influenza, urinary tract infection, sexually transmitted disease, chlamydia, gonorrhea, syphilis, infectious diseases, human immunodeficiency virus, HIV viral load, acquired immune deficiency syndrome (AIDS), herpes simplex virus, hepatitis, cognitive function, Alzheimer disease progression, fertility monitoring, LH, FSH, progesterone, E3, hCG, estrogen, testosterone, nutritional status, nutritional assessment, environmental hazard screening, environmental contaminants, heavy metal, mercury, lead, asbestos, encephalitis, E. coli, diabetes, glucose, glycated proteins, ketones, steroids, cancer markers, drug abuse, toxicology, vitamins, vitamin deficiency, dehydration, specific gravity, smoking, continine, carbon dioxide, asthma, lung cancer, lung capacity, tuberculosis, pneumonia, blood alcohol, gastrointestinal disease, H. Pylori, Ebola virus, colon cancer, colon cysts, colon polyps, occult blood, inflammatory

35 bowl disease, fiber level, allergies, cystic fibrosis, bacteria, RSV, viruses, bacteria infectious organisms, dental assessment, tooth decay, saliva acidity, yeast infections, yeast levels, genetic testing, forensics, toe fungus, athletes foot, pink eye, blood pressure, varicella zoster virus, cytomegalovirus, Epstein barr, papilloma virus, cellulitus, staphylococci, streptococci, mycobacteria, adenovirus; encephalitis, meningitis, arbovirus, 40 arenavirus, anaerobic bacilli, picornavirus, coronavirus, synsyntialvirus, pregnancy, and cholesterol level; said test equipment providing test results selected from the group consisting of test data, information, answers, chemical reaction, chemical analysis, color change, and visual appearance;

45 at least one device for electronically inputting said test results and a medical profile of said patient into a central processing unit, said device being selected from the group consisting of a keyboard, optical scanner, telephone, modem, cellular phone, internet connection, world wide web connection, cable, phone line, computer, and touch screen display;

50 said medical profile comprising patient data selected from the group consisting of a patient's age, sex, height, weight, medical history, current medication, physician, spouse, sex partners, parents, and children;

55 said central processing unit being selected from the group consisting of a microprocessor, computer, computer system, computer network, semiconductor chip, circuit board, control board, programmable controller, logic controller, mainframe, global communications network, satellite system, internet network, world wide web network, and data processing center;

60 a modem connected to said central processing unit for accessing at least one data base, said data base comprising electronic information selected from the group consisting of chronic diseases, infectious diseases, environmental diseases, general health information, fertility, nutrition, medical treatment, prescription drugs, over-the-counter drugs medicine, care maps, treatment guidelines, medical tests, product information, DNA data, sequence listings, and fingerprint information;

65 said central processing unit
electronically analyzing said test results;

electronically comparing said analysis of said test results with said medical profile and data base;

70 generating a diagnosis and a recommendation selected from the group consisting of medical treatment, medicine, dosage, prescription drugs, over-the-counter drugs, nutritional supplements, treatment regimens, exercise, diet, and compliance reminder; and transmitting said diagnosis and recommendation for approval or changes to medical personnel selected from the group consisting of a physician or health care provider;

an inputting device for inputting approval or changes to said diagnosis and recommendation from said medical personnel to said central processing unit to provide feedback for said patient;

75 a transmitter selected from the group consisting of telephone, facsimile machine, and electronic mail, for transmitting to said patient and permitting said patient to access and retrieve said approved or changed diagnosis and recommendation resulting from said sample collection and testing after said central processing unit has verified that a person seeking to access the approved or changed diagnosis and recommendation is said patient.

57. An automatic test reporting system in accordance with claim 56 wherein said test kit is obtained by purchasing said test kit from a facility selected from the group consisting of: a pharmacy; a store; a mail order supply house; and a company advertised on television, radio, newspaper, magazine, catalog, internet or a web site.

80 58. An automatic test reporting system in accordance with claim 56 wherein:
said patient comprises a person selected by said central processing unit at a request of an organization selected from the group consisting of: an insurance company, an integrated health care provider, a managed care provider, health maintenance organization, a medical group, a public health agency, ministry of health, and Center for Disease Control; and
said test kit is delivered to said patient at the request and expense of said organization.

59. An automatic test reporting system in accordance with claim 56 wherein said test equipment is selected from the group consisting of an: immunodiagnostics analyzer, immunoassay system, hematology analyzer, blood screen instrument, blood analyzer, chemistry instrument, chromatograph, urine analyzer, semen analyzer, hair analyzer, tissue and pore analyzer, drug monitor, microbiology analyzer, diagnostics instrument, and diagnostics device.

60. An automatic test reporting system in accordance with claim 56 including an instrument for collecting said samples, said instrument comprising a member selected from the group consisting of a: swab, cotton, gauge, lance, tissue, nail clippers, scissors, cup, bottle, container, test tube, capillary tube, petri dish, condom, bag, glove, tape, blotter, paper, paperboard, cardboard, dermatological patches, eye dropper, pipettes, collector device, sample retriever, and medical instrument.

61. An automatic test reporting system in accordance with claim 56 including a printer connected to said central processing unit for printing said approved or changed diagnosis and recommendation for delivery and confirmation to aid patient and medical personnel, and said printer being selected from the group consisting of a laser printer, an ink jet printer, a dot matrix printer, and an impact printer.

62. An automatic test reporting system in accordance with claim 61 including a facsimile machine operatively associated with said central processing unit for transmitting said printed approved or changed diagnosis and recommendation to said patient and medical personnel.

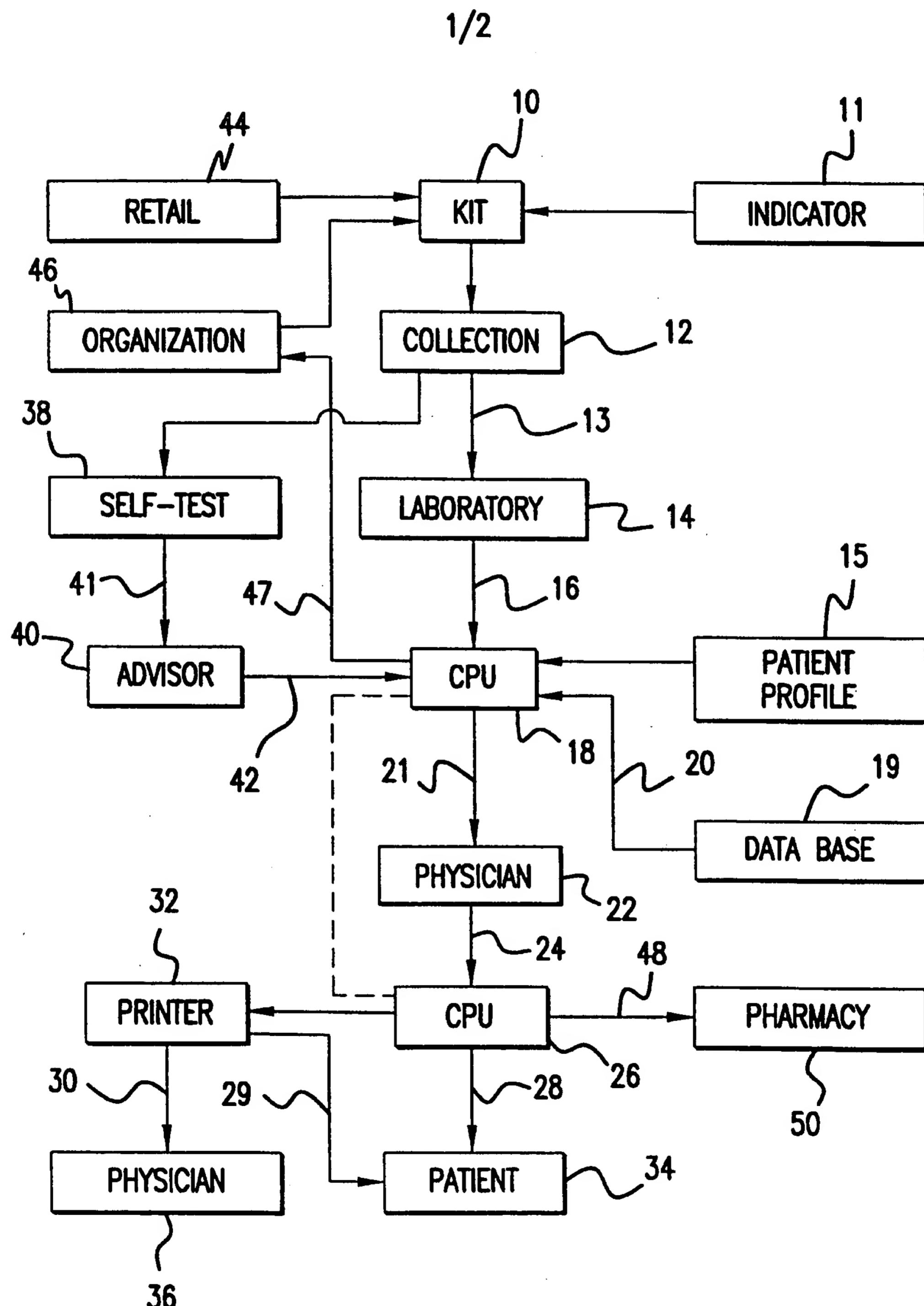


FIG. 1

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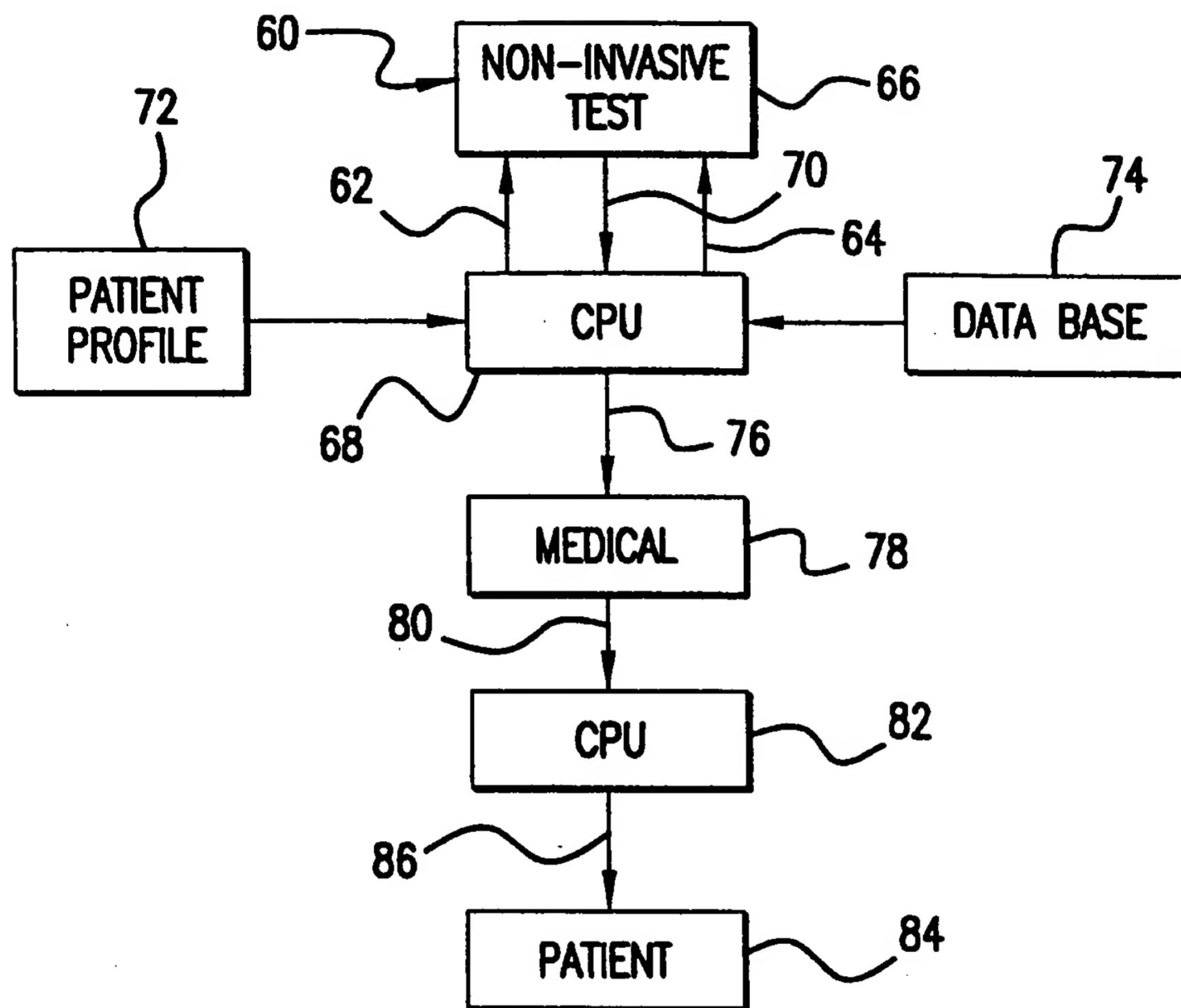


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/13681

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :Please See Extra Sheet.

US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/5, 7.1, 974, 975; 436/518; 422/61; 379/38, 67, 97, 106, 196, 212, 265

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, MAYA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,792,968 A (KATZ) 20 December 1988, see entire document.	1-62
Y	Abstracts of Projects Funded by U.S. Dept. of Commerce. Advanced Technology Program Information Infrastructure for Healthcare. "Healthcare Lifetime Data Repository Infrastructure", October 1994 and 1995, see entire document.	1-62

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

01 OCTOBER 1998

Date of mailing of the international search report

03 DEC 1998

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/13681

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (6):

C12Q 1/70; G01N 33/53, 33/543, 33/564; H04M 1/64, 3/00, 3/42, 11/00, 11/04

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

435/5, 7.1, 974, 975; 436/518; 422/61; 379/38, 67, 97, 106, 196, 212, 265